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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 10/035,821  | 10/19/2001  | Jane Werling         | IDD-5657 CIP2           | 2470             |
| 7590  | 05/06/2004  |                      | EXAMINER                |                  |
| MARK J. BUONAIUTO, ESQ.<br>BAXTER INTERNATIONAL INC.<br>LAW DEPARTMENT<br>ONE BAXTER PARKWAY, DF2-2E<br>DEERFIELD, IL 60015 |             |                      | OH, SIMON J             |                  |
|   |             |                      | ART UNIT                | PAPER NUMBER     |
|   |             |                      | 1615                    |                  |
|   |             |                      | DATE MAILED: 05/06/2004 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/035,821             | WERLING ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Simon J. Oh            | 1615                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 March 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-64 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-64 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicants' request for continued examination, amendment, response, and petition for extension of time, all received on 29 March 2004.

### ***Double Patenting***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The provisional rejection of Claims 1-40 under the judicially created doctrine of double patenting over Claims 98-126 of co-pending Application No. 10/021,692 is rendered moot with the cancellation of those claims in the co-pending application.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-64 under 35 U.S.C. 103(a) as being unpatentable over Stainmesse *et al.* in view of Cima *et al.* is maintained.

### ***Response to Arguments***

Applicant's arguments filed 29 March 2004 have been fully considered but they are not persuasive.

The examiner does not consider the example in Stainmesse *et al.* cited by the applicants to be particularly limiting to the scope of the disclosure of the methods of the prior art. As the methods of the prior art can be applied to various substances, it is the position of the examiner that the state of the particles (crystalline or non-crystalline) produced by the prior art depend upon, or are influenced by the nature of the substance to made into sub-micron particles. Absent a demonstration made by the applicants showing otherwise, the examiner will not consider the scope of the methods of the prior art to be limited solely to the examples disclosed by the prior art.

Accordingly, since the examiner does not interpret the disclosure of the Stainmesse *et al.* patent to be strictly limited in scope to the manufacture of spherical particles, the rejection based upon the combination of disclosures from that reference with the Cima *et al.* patent is deemed proper and is maintained. The claims will remain rejected.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1615

sjo

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600